

EXHIBIT L

In the Matter Of:

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY

30(B)(6) VIDEOTAPED DEPOSITION OF MARTIN KELVAS

August 26, 2015



100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999

<p style="text-align: right;">Page 93</p> <p>1 honestly don't remember the exact year, but it was 2 later on. I -- we may have written it before -- well, 3 it was definitely written before 2012.</p> <p>4 Q. Okay.</p> <p>5 A. That, I know because that's the year I left 6 the organization. We had that policy in place for a 7 couple of years, at least.</p> <p>8 Q. Okay. So it was probably written in 2010, 9 give or take a year?</p> <p>10 A. Yeah, before all this unfolded. Yeah, 11 because we -- again, I was having those discussions 12 and you'll see the documentation in 2011 with the 13 Board of Pharmacy that -- you know, things were 14 changing, and there was no clear guidance in the 15 industry for these changes. It's unfortunate.</p> <p>16 Q. So let me ask you about this conversation 17 with Terry Grinder. Is it your understanding, then, 18 that if a hospital were to purchase a compounded 19 pharmaceutical product and then resell it, they would 20 be in violation of Tennessee State law?</p> <p>21 A. If -- that was what I was led to believe, 22 yes.</p> <p>23 Q. And by the same token, if they were then to 24 bill Medicare for that product, they would have real 25 federal trouble as well; correct?</p>	<p style="text-align: right;">Page 95</p> <p>1 he has it in front of him and he doesn't 2 have to speculate? We provided it to you. 3 We've got it. Do we send it to Mark 4 Zamora?</p> <p>5 MR. HOFFMAN: Send it to the 6 assistant.</p> <p>7 VIDEOGRAPHER: 3:02 p.m., off the 8 record.</p> <p>9 (A recess was taken.)</p> <p>10 VIDEOGRAPHER: 3:15 p.m., back on the 11 record.</p> <p>12 Q. (By Mr. Stranch) Okay. So the time period 13 in which you spoke with Terry Grinder was 14 approximately early 2011; correct?</p> <p>15 A. Yes. I believe it was March.</p> <p>16 Q. Okay. Let me ask you real quick. We've 17 taken two breaks here. Did you discuss your testimony 18 with anyone during the breaks?</p> <p>19 A. Just that I'm doing okay and, you know, 20 don't be so nervous and just relax and don't -- you 21 know, just speak clearly and, you know -- I had a 22 little confusion about when I should or should not 23 speak, but, you know, just some clarification about 24 objections. I'm trying to follow proper direction.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 94</p> <p>1 MS. PUIG: Object to form.</p> <p>2 MR. TARDIO: Object to form.</p> <p>3 MS. PUIG: He's not being offered 4 here as a lawyer or to offer any legal 5 conclusions.</p> <p>6 Go ahead.</p> <p>7 Q. (By Mr. Stranch) You can answer.</p> <p>8 A. My understanding was we were not allowed to 9 bill for the product. Whether or not CMS or any -- 10 you know, or the federal government had the same 11 interpretation, I don't know. All I know is from the 12 Board of Pharmacy from Tennessee said, no, you can't 13 do that. But I had nothing in writing. I had no rule 14 or law to look at to tell me that that, in fact, was 15 correct. I was going by a verbal interpretation from 16 inspector from the Board of Pharmacy.</p> <p>17 Q. Okay.</p> <p>18 A. Because they're the ones who come in and 19 knock on my door and say, I'm here to inspect your 20 pharmacy. So I answered to them. So I follow what 21 they tell me. When they say jump, I say how high.</p> <p>22 Q. Okay. When was this -- approximately, when 23 was this conversation with Mr. Grinder?</p> <p>24 MS. PUIG: Can we take a break and go 25 off the record and print it for him so that</p>	<p style="text-align: right;">Page 96</p> <p>1 A. That's all.</p> <p>2 Q. Okay. Good.</p> <p>3 MR. GASTEL: I'm confused by Yvonne's 4 objections, too.</p> <p>5 MS. PUIG: I'm going to object to 6 your objection.</p> <p>7 THE WITNESS: I think I'm walking 8 home.</p> <p>9 MR. STRANCH: We'll give you a ride. 10 Don't worry.</p> <p>11 MS. PUIG: That would be quite awry. 12 I want to be the hood ornament for that car 13 ride.</p> <p>14 Q. (By Mr. Stranch) Okay. So I want to try 15 to talk about this conversation with Terry Grinder. 16 My understanding of your -- and I may be putting words 17 into your mouth, and so if I do, please correct me. 18 I'm not trying to.</p> <p>19 My understanding is that Mr. Grinder told 20 you that you could not purchase from -- as a hospital, 21 you could not purchase from a compounding pharmacy in 22 bulk and then hold it and resell it; is that correct?</p> <p>23 A. He went a step further. He said you can't 24 buy any product from them and resell it. It had, you 25 know, this relationship of one prescription, one drug.</p>

<p style="text-align: right;">Page 97</p> <p>1 He gave me the illustration of a triangle. You have 2 the physician, the patient and the pharmacy. You're 3 now putting a second pharmacy in this triangle. 4 Doesn't belong there. That's the problem. It was a 5 great illustration.</p> <p>6 So having two pharmacies, it's -- your one 7 pharmacy is compounding for the other pharmacy, and 8 it's selling to one and then the pharmacy is selling 9 again to the patient. He said that -- that, in his 10 interpretation was not legal.</p> <p>11 Q. Okay.</p> <p>12 A. That's the problem.</p> <p>13 Q. But this -- your understanding is this 14 would have been okay if the second compounding 15 pharmacy had held a manufacturer's license; correct?</p> <p>16 A. That is correct.</p> <p>17 Q. Okay.</p> <p>18 A. Because now it's not a pharmacy. It's a 19 manufacturer. That's a different entity, a different 20 licensure. They're licensed in the State of Tennessee 21 as a manufacturer or they're -- they're licensed 22 somewhere as a manufacturer and inspected by the FDA.</p> <p>23 Q. Okay.</p> <p>24 A. So you can do that. That's the model that 25 works.</p>	<p style="text-align: right;">Page 99</p> <p>1 Repackaging, compounding, whatever. So that's a safe 2 product and labeling that product in a hospital 3 setting so that the nurse can administer it.</p> <p>4 It's different than retail. So we won't go 5 to retail discussion right now.</p> <p>6 Q. But the situation in which -- okay. So 7 that would be the pharmacy's responsibility as to 8 patient safety in the traditional three triangle 9 without the pharmacy being a retail pharmacy; correct?</p> <p>10 A. In a hospital setting.</p> <p>11 Q. In a hospital setting?</p> <p>12 A. Yeah.</p> <p>13 Q. Would that also apply to in a clinical 14 setting, like an ambulatory surgery center?</p> <p>15 MR. KRAUSE: Object to the form.</p> <p>16 Q. (By Mr. Stranch) You can answer the 17 question.</p> <p>18 A. It's a different scenario. In a clinic 19 setting, there's no pharmacy. Again, we can talk all 20 afternoon about how I feel about that, but that's my 21 philosophy and that's a whole different discussion.</p> <p>22 The triangle is different, if you will. The 23 relationship, you have the patient and the doctor and 24 the clinic. There's no pharmacy necessarily in that 25 equation. The clinic, the physician is allowed to buy</p>
<p style="text-align: right;">Page 98</p> <p>1 Q. Okay.</p> <p>2 A. Yeah.</p> <p>3 Q. And so within this triangle that you just 4 described, who within that triangle of patient, 5 doctor, pharmacy is responsible for patient safety?</p> <p>6 A. They all are, including the patient.</p> <p>7 Q. Okay.</p> <p>8 A. Everyone has a responsibility.</p> <p>9 I mean, we could spend the rest of the 10 afternoon talking about patient safety. I'm trying to 11 answer your questions and be specific.</p> <p>12 Q. I appreciate that.</p> <p>13 A. Yeah.</p> <p>14 Q. And that's why I'm asking.</p> <p>15 So within the triangle, for the patient 16 safety, the -- what would be the pharmacy's 17 responsibility as it relates to patient safety?</p> <p>18 A. Patient safety starts with receiving the 19 order from the physician. So that you do due 20 diligence to reviewing the order to make sure it's the 21 right drug for the right patient, the right dose. 22 There's no contraindications. No drug-drug 23 interactions, so on and so forth.</p> <p>24 And then the preparation of the product, 25 whatever that is, if there is preparation involved.</p>	<p style="text-align: right;">Page 100</p> <p>1 and purchase pharmaceuticals. Now we're talking about 2 a different class of trade now. There's no pharmacy 3 in that equation. Do I agree with that? Well, that's 4 my own -- I have my own opinion. I'm not going to go 5 there right now.</p> <p>6 But you have a physician and a patient 7 relationship that is protected, and the physician can 8 purchase drugs. They're allowed to do that. They're 9 licensed to do so, and they can administer it to the 10 patient. There's no pharmacy involved in that 11 equation. We're out of the loop.</p> <p>12 Q. Briefly, what is your -- what is your 13 concern with that setup?</p> <p>14 MR. TARDIO: Object to the form.</p> <p>15 THE WITNESS: Yeah. I mean, my 16 opinion has maybe no bearing on this 17 because the law allows it and it's 18 considered legal, and the physician is 19 assuming the responsibility to whatever 20 they buy, it's a good product, reliable and 21 meets all the requirements before the drug 22 is utilized and administered to the 23 patient. The nurse may administer it so 24 the doctor usually does -- well, sometimes 25 the doctor, but it depends on the</p>

<p style="text-align: right;">Page 101</p> <p>1 situation, of course.</p> <p>2 So it's a legal process. It's there.</p> <p>3 It's all legal. All the checks and</p> <p>4 balances should be there. The knowledge</p> <p>5 base of the physician and the clinicians</p> <p>6 working in that clinic, they assume all</p> <p>7 those responsibilities. When there's no</p> <p>8 pharmacist in the equation, somebody else</p> <p>9 has to take on that responsibility and have</p> <p>10 that knowledge.</p> <p>11 Q. (By Mr. Stranch) So within that triangle,</p> <p>12 the physician is both the physician and serves wearing</p> <p>13 the hat of the pharmacist; correct?</p> <p>14 A. You could say that.</p> <p>15 Q. Is that your understanding of how it works?</p> <p>16 A. Well, there's clearly no pharmacist in the</p> <p>17 equation so there's no triangle. There's no triangle.</p> <p>18 It's one to one, physician, patient. There's no</p> <p>19 triangle.</p> <p>20 Q. So the portion of patient safety that the</p> <p>21 pharmacist would take care of in the triangle that</p> <p>22 relates to the drug itself, that now falls solely on</p> <p>23 the physician; correct?</p> <p>24 A. And the nurse administering it, if there's</p> <p>25 a nurse involved.</p>	<p style="text-align: right;">Page 103</p> <p>1 A. That would be my understanding.</p> <p>2 Q. Okay. And so the physician would need --</p> <p>3 would need to fulfill the role that the pharmacist</p> <p>4 would normally fulfill in that -- in the triangle;</p> <p>5 correct?</p> <p>6 A. That's my understanding.</p> <p>7 Q. And as a pharmacist, in the triangular</p> <p>8 role, you would only purchase from a manufacturer that</p> <p>9 has a manufacturer's license; correct?</p> <p>10 A. Before 2012 or after?</p> <p>11 Q. Before 2012.</p> <p>12 A. Before 2012, my understanding, my</p> <p>13 interpretation, yes, I'd only buy from a</p> <p>14 manufacture -- a company with a manufacturer's</p> <p>15 license.</p> <p>16 Q. So what was happening in March of 2011 that</p> <p>17 led to you reach out to Terry Grinder? You referenced</p> <p>18 earlier about things were changing. Can you explain</p> <p>19 that.</p> <p>20 MS. PUIG: Can I hand him this to</p> <p>21 refresh his recollection?</p> <p>22 MR. STRANCH: Oh, sure. Sure.</p> <p>23 THE WITNESS: Yeah. This is, I</p> <p>24 guess --</p> <p>25 Q. (By Mr. Stranch) Let's start with would</p>
<p style="text-align: right;">Page 102</p> <p>1 Q. Okay.</p> <p>2 A. Yeah.</p> <p>3 Q. Okay. So it would be up to the physician</p> <p>4 to -- if they're going to order in bulk, to order in</p> <p>5 bulk from someone with a manufacturing license;</p> <p>6 correct?</p> <p>7 MR. TARDIO: Object to the form.</p> <p>8 MS. PUIG: Again, object to form.</p> <p>9 He's not being offered as an expert. He's</p> <p>10 testified he is not knowledgeable about</p> <p>11 physician practices or ASC internal</p> <p>12 practices. I'm going to object.</p> <p>13 You can answer if you know but -- if</p> <p>14 you know.</p> <p>15 THE WITNESS: I'm -- you'll have to</p> <p>16 restate the question. I want to make sure</p> <p>17 I understand this question before I answer</p> <p>18 it.</p> <p>19 Q. (By Mr. Stranch) So the question is, in a</p> <p>20 situation where the physician is wearing the</p> <p>21 pharmacist hat, the physician would also have the</p> <p>22 responsibility of making sure when they order the</p> <p>23 product, that they're keeping the patient safety in</p> <p>24 mind as you have to do when it's the triangle setup;</p> <p>25 correct?</p>	<p style="text-align: right;">Page 104</p> <p>1 you like to identify this document and let's go ahead</p> <p>2 and mark it as 537.</p> <p>3 A. Sure. So I'll just take a moment to</p> <p>4 explain what this is?</p> <p>5 (Exhibit 537 was marked for</p> <p>6 identification.)</p> <p>7 MR. FITZPATRICK: Yes, you can.</p> <p>8 THE WITNESS: Okay. This is a</p> <p>9 compounding agreement between NECC -- a</p> <p>10 proposed compounding agreement that they</p> <p>11 had, form letter, if you will, between NECC</p> <p>12 and any facility, hospital, probably could</p> <p>13 be a doctor's office, too, that wanted to</p> <p>14 purchase their products. The sales rep</p> <p>15 came in to see me, and her name is on here,</p> <p>16 Susan Maynard. She came in to see me on</p> <p>17 March 28th, and I believe that's 2011. I</p> <p>18 read my own scribble.</p> <p>19 And I looked at this and I had</p> <p>20 discussion with her and said, we can't do</p> <p>21 this. And to make a long story short, she</p> <p>22 said, oh, yeah, you know, we're doing this</p> <p>23 all over. As long as you provide us a list</p> <p>24 of patients, we can -- you know, we can</p> <p>25 send you the drug and then you can send us</p>

<p style="text-align: right;">Page 105</p> <p>1 of list of patients you're using it for. 2 It's legal. And I said, no, that's not my 3 understanding. And she explained to me 4 this is being done all over the country, 5 and I said, well, that may be so, but I'm 6 not comfortable with this.</p> <p>7 So we parted company after a 8 discussion, and the next day, I dated it 9 3/29/2011, I called Terry Grinder, Board of 10 Tennessee, and he said, you cannot do this. 11 And I wrote it, cannot do this. I stapled 12 the sales rep's card to this, documented it 13 and said one day I may need this and 14 plopped it in a file. They -- a lot of 15 people think I'm nuts because I save all 16 this stuff, at least when I worked at St. 17 Thomas, but I'm glad I did because we 18 discovered this or it was discovered and it 19 was still in the file after I left.</p> <p>20 So that's the long and short of it. 21 So I'll let you ask your questions.</p> <p>22 Q. (By Mr. Stranch) Why were you not 23 comfortable with this proposal?</p> <p>24 A. I had had an earlier discussion years 25 before this with the Board of Pharmacy, very same</p>	<p style="text-align: right;">Page 107</p> <p>1 be buying from FDA-approved manufacturers, AB-rated 2 drugs and so on. We began visiting this whole thing 3 in some of our policies.</p> <p>4 But there was no written directive for me 5 because I had nothing in writing to substantiate what 6 the Board of Pharmacy interpretation was to me. I had 7 nothing in writing anywhere. I couldn't find it. So 8 I'm like, you know, I'm stuck. So I have to go by 9 what I was told.</p> <p>10 Q. Beyond the concerns about whether it was 11 legal or not, did you have any patient safety concerns 12 about ordering from a compounding pharmacy?</p> <p>13 A. At that time, it wasn't so much about 14 safety as it was the regulatory issues. I was aware 15 that other places were buying this stuff and using it, 16 not specific to NECC, but just compound -- there are 17 compounding pharmacies all over the country popping 18 up, and you hear people talking and they're buying 19 from these compounding pharmacies and using the 20 product and not having any problems.</p> <p>21 So in my mind, it wasn't at that time 22 safety so much as it was regulatory issues. I needed 23 to find out from the Board of Pharmacy are we allowed 24 to do this. Can a compounding pharmacy act like a 25 manufacturer? That was my concern, the legalness of</p>
<p style="text-align: right;">Page 106</p> <p>1 thing, and I was -- wanted to see if anything had 2 changed. I don't remember when that call was, but it 3 was years -- maybe five years before this.</p> <p>4 The whole industry was changing because of 5 drug shortages, and the compounding pharmacies were 6 beginning to have a presence, but there was no clear 7 interpretation or enforcement of any rules or regs, 8 how far can a compounding pharmacy go in preparing 9 product and then selling that not only to patients, to 10 doctors' offices or even out of state.</p> <p>11 I called the Board of Pharmacy with the 12 same question, and I got the same exact answer with a 13 little bit more clarity perhaps from Terry Grinder 14 this time. I'm not sure who I spoke to the first 15 time, but I got this -- I wanted to see if anything 16 has changed. Nothing had changed. Even though what I 17 was seeing around me happen, I was hearing more and 18 more of other places reconsidering and perhaps even 19 purchasing product from them, but I -- I called the 20 board and got my own clarification and said this is 21 the way we're going to do it. And I verbally 22 communicated that to my buyers, to my staff, made it 23 very clear, and that's when we began looking at our 24 own internal procedures and policies about how could 25 we clarify some of that. We focused on what we should</p>	<p style="text-align: right;">Page 108</p> <p>1 it. I had no idea that all this was going to happen.</p> <p>2 Q. But you would agree with me, though, that 3 the regulations are there to help protect patient 4 safety; correct?</p> <p>5 A. Yes.</p> <p>6 MR. TARDIO: Object to the form.</p> <p>7 THE WITNESS: I mean, that's what we 8 have rules and regs for. Pharmacy is a 9 highly regulated profession, probably more 10 than any other healthcare profession that 11 I'm aware of. You ever see our pharmacy 12 law books? That's why --</p> <p>13 Q. (By Mr. Stranch) Unfortunately, yes.</p> <p>14 A. Yeah. So I'm preaching to the choir.</p> <p>15 It's -- but that's who we are. And that's 16 what we do, right.</p> <p>17 Q. And the regulations that are on a licensed 18 manufacturer are much greater than the ones that are 19 on just a compounding pharmacy; correct?</p> <p>20 A. They're different and they -- you used the 21 word "more restrictive." I would like to use the word 22 "they're a guidance" to say that in this setting, you 23 can do this, and in this setting you can do that. And 24 again, as I mentioned earlier, that it's about 25 compounding and expiration dates, stability,</p>

<p style="text-align: right;">Page 109</p> <p>1 sterility. In the compounding pharmacy, you do not 2 have the same rules and regulations and requirements 3 for clean rooms and so on. Good manufacturing 4 procedures are more stringent in the manufacturing 5 than they are in the compounding pharmacy.</p> <p>6 Q. Okay. So if I'm understanding you 7 correctly, the regulations that are placed on a 8 licensed manufacturing facility are much more 9 stringent than those that are placed on a compounding 10 pharmacy; is that correct?</p> <p>11 MR. KRAUSE: Object to the form.</p> <p>12 THE WITNESS: Before 2012?</p> <p>13 Q. (By Mr. Stranch) Before 2012.</p> <p>14 A. Yes.</p> <p>15 Q. During this time that you just described 16 where compounding pharmacies were starting to crop up 17 and people were starting to order from them, did you 18 discuss this with other pharmacists about any concerns 19 you had or questions or things that they were seeing?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. What would those discussions 22 generally center on or how would they -- what would 23 generally be the tenor of those discussions?</p> <p>24 A. After my discussion with Terry Grinder, I 25 picked up the phone within the next day or two and</p>	<p style="text-align: right;">Page 111</p> <p>1 MS. PUIG: He said his sister 2 hospitals.</p> <p>3 THE WITNESS: Sister hospitals which 4 would be -- you know, at that time, it 5 was -- I know they changed the names of the 6 hospitals, but it was Baptist and MTMC. 7 Our ministry, local ministry. I wasn't --</p> <p>8 Q. (By Mr. Stranch) Okay.</p> <p>9 A. Too many -- you know, hey, I don't have the 10 time to start calling everybody. I -- but I called 11 who I felt I -- within our system, as we typically do, 12 we share information. That's what we do.</p> <p>13 Q. Okay. Did you call -- okay. In these 14 discussions that you had with your sister hospitals in 15 the Nashville area or middle Tennessee area, was there 16 any discussion about NECC, in particular?</p> <p>17 A. I am -- I believe so. I probably cited the 18 fact that the sales rep came to see me. They're 19 probably coming to see you. I called the board about 20 this and specific to this company, but it would apply 21 to any compounding pharmacy, whether it was NECC, 22 because we were being contacted by other compounding 23 pharmacies, also, not just this company.</p> <p>24 Q. So let me ask you about that meeting with 25 Ms. Maynard. What was it about this document or your</p>
<p style="text-align: right;">Page 110</p> <p>1 called my colleagues at my sister hospitals within the 2 Nashville ministry and told them of what I learned and 3 made them aware of what I learned. And I thought that 4 was my responsibility, and they had to make their 5 decisions based on the information I was sharing with 6 them.</p> <p>7 If I remember correctly, I believe they 8 were telling me at that point in time -- I don't -- I 9 don't believe they were buying from compounding 10 pharmacies. So I think we were okay at that time. 11 But I did share that with them.</p> <p>12 There were a lot of questions and where is 13 it in writing, Marty? Well, I don't have anything in 14 writing. You know, people want to see it in writing, 15 not just, well, you're just telling me verbally what 16 is -- you know, I don't have anything in writing. I 17 don't.</p> <p>18 Q. So you felt that this was a very important 19 issue, didn't you?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And you say you communicated with 22 the pharmacists at other hospitals in town. Did 23 that -- is that people at Vanderbilt, people at what 24 was Baptist, people at -- or only within the St. 25 Thomas community?</p>	<p style="text-align: right;">Page 112</p> <p>1 meeting with Ms. Maynard that caused you to say this 2 is the one that's going to require me to call the 3 Board of Pharmacy?</p> <p>4 A. Because she was the one that came to see me 5 face to face and she was insistent that this was okay 6 and cited all kinds of examples. So I'm like maybe 7 something's changed. Let me call again. Maybe I'm 8 wrong. Again, I just had nothing in writing. It's 9 one person's interpretation from a previous phone call 10 maybe five years before. So I said, you know what, I 11 need to call again, and I got the same answer. And 12 I -- and I told the Board of Pharmacy, I said, are you 13 aware of what's going on with this company? They 14 said, we'll look into it. That was the end of the 15 conversation.</p> <p>16 Q. Did you discuss your concerns with any 17 other members of the local pharmaceutical -- or 18 pharmacy community, either at any meetings or any 19 trade groups or anything of that nature?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Tell me about with who, what 22 meetings, what trade groups.</p> <p>23 A. I wanted to know what other people were 24 doing. Was this just a Tennessee issue? What was 25 going on in other states because we have other</p>

<p style="text-align: right;">Page 117</p> <p>1 Tennessee. According to this sales rep, 2 she said they were buying it at other 3 hospitals in Tennessee, and I'm like I'm 4 not going there.</p> <p>5 Q. (By Mr. Stranch) Did you ever speak with 6 Mike O'Neil at -- do you know who Mike O'Neil at 7 Vanderbilt is?</p> <p>8 A. I've heard the name, but I don't know him 9 personally.</p> <p>10 Q. Okay. You worked also with the Belmont 11 pharmacy school; correct?</p> <p>12 A. That is correct.</p> <p>13 Q. Okay. Did you discuss this with anyone at 14 the Belmont pharmacy school?</p> <p>15 A. Not that I can recall. This really 16 wasn't -- we may have talked about drug shortages, in 17 general, but not about NECC, no. You know, that's -- 18 that's more of the education side of things. They're 19 not into buying and selling drugs at all. So I don't 20 think that really came up.</p> <p>21 MS. PUIG: Do you have a name --</p> <p>22 THE WITNESS: Not that I recall.</p> <p>23 MS. PUIG: -- at Belmont pharmacy 24 school?</p> <p>25 MR. STRANCH: No. I'm just asking</p>	<p style="text-align: right;">Page 119</p> <p>1 But usually, those kind of -- we discourage 2 that kind of relationship because, inevitably, it 3 would lead to things we could not get involved in with 4 them. Even if they're dealing with drug shortages, I 5 can't help you. There's nothing I can do for you.</p> <p>6 Q. Yeah. So if someone from the for-profit 7 side had contacted you about potentially purchasing 8 from a -- drugs from a compounding pharmacy in bulk, 9 would you have discouraged that purchase?</p> <p>10 A. I would have probably told them what we're 11 doing and why and they have to make their own 12 decision. They're a different class of trade. So the 13 triangle doesn't exist. So they're outside the 14 triangle, which means they're allowed to buy drugs on 15 their own. And --</p> <p>16 Q. And then --</p> <p>17 A. They're not regulated by the Board of 18 Pharmacy, per se. They're by the Board of Medicine. 19 However, if they do get involved -- you know, I'm not 20 an expert on where the Board of Pharmacy -- I mean, I 21 guess they could inspect the doctor's office if they 22 wanted to, but that's kind of unusual. Usually, they 23 do that when there's a problem. It's not usual for 24 them to inspect doctors' offices.</p> <p>25 So they're a different class of trade.</p>
<p style="text-align: right;">Page 118</p> <p>1 questions.</p> <p>2 Q. (By Mr. Stranch) Mike O'Neil is at 3 Vanderbilt School of Pharmacy?</p> <p>4 A. Okay.</p> <p>5 Q. Does that help jog your memory on who he 6 is?</p> <p>7 A. Little bit. Maybe that's why I recognize 8 the name. I may have met him, may have talked with 9 him, but he may be one of the professors there. I 10 don't know. I mean, I've been away from it for a 11 while.</p> <p>12 Q. Okay.</p> <p>13 A. Yeah.</p> <p>14 Q. Did you speak with a Mrs. Beckom?</p> <p>15 A. I may have. Of course, her name has become 16 much more familiar to me because of this whole 17 litigation, but prior to that, I probably interacted 18 with her maybe once or twice. They may have called 19 with a question. But we made it very clear to them 20 who are you and what's your clinic and, oh, you're not 21 part of the network. Okay. You're at the for-profit 22 side. What are your questions? We can't help you 23 with any drug procurement, any sales or anything like 24 that. They may have had possibly some procedural 25 questions. I don't know. I don't remember.</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. Yeah. So if someone from that for-profit 2 side that is in that different class had contacted 3 you, would you have at least encouraged them to 4 contact the Board of Pharmacy or Board of Health to 5 determine whether they could be doing this?</p> <p>6 A. I don't know. Like I said, that didn't 7 happen. I never spoke to them about it. I didn't 8 even think of calling them because we -- you know, the 9 line is drawn in the sand. They're over there in the 10 for-profit world. We're in the nonprofit world. Our 11 worlds did not -- we did not mesh. We didn't talk to 12 each other, really.</p> <p>13 So if they had called me, as an inference, 14 I would have told them what we're doing, and I would 15 have explained to them why. But then again, I might 16 have said to them -- first of all, at that point in 17 time before 2012, we had no concern at that point so 18 much about the safety of the product. It was more 19 about the regulatory issue, and being a different 20 class of trade, I couldn't speak to that for the 21 doctor's office. They're outside of that triangle.</p> <p>22 Q. But if a clinic or a doctor's office was 23 trying to meet the same standards, the same high 24 standards that you meet and provide through your 25 pharmacy, you would have discouraged them from</p>

<p style="text-align: right;">Page 161</p> <p>1 bucket? MPA.</p> <p>2 Q. MPA that's been produced in bulk, that as</p> <p>3 orders came in --</p> <p>4 A. I mean, is the bucket sterilized? Is it</p> <p>5 clean? I don't know, you know. I don't -- you know,</p> <p>6 I mean, there's a lot of questions that have to be</p> <p>7 asked. Unless you're there inspecting it, it's</p> <p>8 hard -- you know, I'm just looking at a picture that's</p> <p>9 very fuzzy and is it -- is it a sterilized bucket? I</p> <p>10 don't know.</p> <p>11 Q. Yeah.</p> <p>12 A. I don't know.</p> <p>13 Q. But does that in general raise red flags</p> <p>14 where you'd want to ask a lot of questions because of</p> <p>15 that?</p> <p>16 A. Sure.</p> <p>17 Q. Okay. Flip over to the first page. You</p> <p>18 see the filthy sticky mats rest on processing</p> <p>19 equipment, missing ceiling tiles in a clean room,</p> <p>20 ceiling penetrations in a clean room? Would these be</p> <p>21 all things that would lead to you to raise -- that</p> <p>22 would raise questions in your mind that would need to</p> <p>23 be addressed?</p> <p>24 MS. PUIG: Object to the form.</p> <p>25 THE WITNESS: Yes.</p>	<p style="text-align: right;">Page 163</p> <p>1 end of March 2011, you were contacted by a rep from</p> <p>2 NECC trying to convince you that they can do business</p> <p>3 with you; correct?</p> <p>4 A. That is correct.</p> <p>5 Q. You contacted Terry Grinder at the</p> <p>6 Tennessee Department of Health or Board of Pharmacy to</p> <p>7 inquire about whether you could do business with a</p> <p>8 compounding pharmacy; correct?</p> <p>9 A. Yes.</p> <p>10 Q. And you informed NECC at that time that</p> <p>11 they -- that you could not do business with them;</p> <p>12 correct?</p> <p>13 A. Yes, I did.</p> <p>14 Q. And you also informed your direct -- people</p> <p>15 that directly reported to you and your staff members</p> <p>16 that they're not to do business with a compounding</p> <p>17 pharmacy at that time; correct?</p> <p>18 A. That's correct.</p> <p>19 Q. That included Ms. Leffler, Mr. Neu and who</p> <p>20 else was informed of that?</p> <p>21 A. I don't remember everyone who was there but</p> <p>22 I -- you know, when you give a directive to your</p> <p>23 managers, they're supposed to pass it on down to the</p> <p>24 people who are responsible.</p> <p>25 Q. Yeah.</p>
<p style="text-align: right;">Page 162</p> <p>1 MS. PUIG: Go ahead.</p> <p>2 THE WITNESS: I mean, looking at</p> <p>3 these pictures, yes.</p> <p>4 Q. (By Mr. Stranch) Flip over --</p> <p>5 A. I don't know where these pictures were</p> <p>6 taken, but I'm assuming that's --</p> <p>7 MS. PUIG: It's two years later,</p> <p>8 July 9, 2014 site inspection.</p> <p>9 THE WITNESS: Oh, this is two years</p> <p>10 later. Okay. Yeah. Okay. Sorry. I</p> <p>11 didn't see that.</p> <p>12 But, I mean, these -- yeah, these</p> <p>13 are -- this is not -- this is not a clean</p> <p>14 room, guys.</p> <p>15 Q. (By Mr. Stranch) Yeah. Flip over to the</p> <p>16 second page. These are the sorts of things that if</p> <p>17 you saw them, you would be concerned and want to ask a</p> <p>18 lot of followup questions; correct?</p> <p>19 A. Absolutely. Yes.</p> <p>20 Q. Okay. So to make sure we're keeping</p> <p>21 ourselves in the correct time frame, in early 2011,</p> <p>22 there was a purchase from NECC that Ms. Leffler</p> <p>23 discovered and informed you of and you ordered it</p> <p>24 destroyed.</p> <p>25 Shortly after that, approximately March --</p>	<p style="text-align: right;">Page 164</p> <p>1 A. I -- I don't recall exactly who was in the</p> <p>2 room when I made the comment, but I made it very</p> <p>3 clear. I said, you know, Carmine -- Carmen, I said,</p> <p>4 we have to make sure that Chris Roberts understands</p> <p>5 that we cannot order from any compounding pharmacies,</p> <p>6 and when we have any relationship with any new vendor,</p> <p>7 we have to ask the questions. We have to -- these</p> <p>8 companies were -- unless you asked the right questions</p> <p>9 and got the right documents, it could be misleading.</p> <p>10 And we discovered that very quickly, this being one of</p> <p>11 the examples. I said, from now on, I want -- every</p> <p>12 vendor we deal with, I want a copy of their licensure.</p> <p>13 I want to know exactly if they're a manufacturer, a</p> <p>14 compounding pharmacy or what.</p> <p>15 This kind of opened up the whole floodgate</p> <p>16 for us. I said, you know what, we've got to be</p> <p>17 squeaky clean on this. So that's again -- and I said,</p> <p>18 we need to relook at some of our policies. So we</p> <p>19 began the process of how do we tighten up our ship.</p> <p>20 Q. Good. I'm going to hand you a document.</p> <p>21 It was previously marked Exhibit 528. I'm going to</p> <p>22 ask if you can take a look at this and if you've ever</p> <p>23 seen this.</p> <p>24 A. The first time I saw this document was</p> <p>25 yesterday. My attorneys put this document in front of</p>

<p style="text-align: right;">Page 165</p> <p>1 me and said, Marty, have you ever seen this before? I 2 said, no. I don't know who this individual is. I've 3 never seen this before. I don't remember ever meeting 4 this person, and I'm assuming that they were a rep for 5 the New -- NECC, New England Compounding Pharmacy. 6 Looks like they registered on our VCS site, 7 but I don't recall or remember meeting with this 8 person. It's interesting that it's April, which is a 9 month after I just met with this other person. So why 10 they would be doing this --</p> <p>11 Q. It's April 2012. 12 A. Oh, yeah. I'm sorry. 13 Q. So it's 13 months later. 14 A. I'm sorry. It's a year later. Okay. 15 Thanks for correcting me. So it is a year later. 16 I wonder if they had a new sales rep. I 17 don't know.</p> <p>18 Q. Yeah. So this document, is this something 19 that when a new vendor comes, they're automatically 20 handed, this document, or is this a document that's 21 only given out once you're going to do business with a 22 vendor?</p> <p>23 A. If -- the policy, as I recall, when a 24 vendor first shows up at our door, it's their first 25 visit, we excuse them, and we may meet with them</p>	<p style="text-align: right;">Page 167</p> <p>1 your vaccinations, whatever, et cetera, 2 et cetera. 3 So it's kind of done at a generic 4 level, and that just allows them to get 5 into our organization, then set up 6 appointments to meet with individuals. So 7 I don't know how far --</p> <p>8 Q. (By Mr. Stranch) Okay. And would they 9 sign this document to get into anything within the St. 10 Thomas Health community or would they have a separate 11 one for St. Thomas Hospital, for St. Thomas Health, 12 for any of the clinics, et cetera?</p> <p>13 A. My understanding at the time was that this 14 would let them into any -- anything in the St. Thomas 15 campus, our hospitals. They're in the system and the 16 system was for -- this computerized system was -- they 17 had access -- they only had to do this once. They 18 could get into all the hospitals and any of the 19 clinics that they wanted to because they're now 20 registered in our system.</p> <p>21 Q. Okay. 22 A. Yeah. 23 Q. And so was there some sort of a thing like 24 a tickler or a thing that would have kicked out to let 25 you know here's a new vendor on the pharmacy side</p>
<p style="text-align: right;">Page 166</p> <p>1 briefly, but we instruct them that they are required, 2 the next time they come in, to register VCS. And they 3 are usually given that big packet that has the policy 4 and tells them what they're required to do. 5 So the next time they come in, they're 6 expected to do this, and if they don't, they won't 7 be -- we won't meet with them. They're asked to 8 leave.</p> <p>9 Q. Okay. So Mr. Giomi would have filled this 10 out because he would have been coming to meet with 11 someone about NECC doing work for St. Thomas sometime 12 around April 23rd, 2012 or at some point after that; 13 correct?</p> <p>14 MS. PUIG: Object to form. 15 THE WITNESS: I don't know what 16 happened. It could be a new sales rep. 17 The process at St. Thomas Hospital 18 was they had to go to the security 19 department, and that's where this took 20 place, the registration. They didn't come 21 to the pharmacy. So, you know, the 22 individual in the security department just, 23 okay, this is -- you're a sales rep. Go 24 ahead and fill this out. Read this. 25 Register in the system. Make sure you have</p>	<p style="text-align: right;">Page 168</p> <p>1 that's -- that's filled out this form that's going to 2 be coming in?</p> <p>3 A. No. 4 Q. Okay. 5 A. Unless you went into the system and 6 generated reports. 7 Q. Okay. 8 A. There was no automated process. Yeah. 9 Q. Okay. So you only would have learned of 10 this if Mario decided to come and meet with you or 11 tried to set up an appointment with you? 12 A. Yes, that is correct. 13 Q. Okay. And at this point in time, 13 months 14 after you spoke with Mr. Grinder, your -- it was your 15 understanding that your policy was clear throughout 16 the hospital that there was to be no dealing with 17 compounding pharmacies; correct? 18 A. I think I need to clarify that in that we 19 would not purchase from them. It doesn't mean we 20 couldn't talk to them. 21 Q. So they're welcome to bring you lunch, but 22 you're not going to buy from them? 23 A. No. No. We would not -- they were not 24 allowed to bring us lunch without an educational 25 program.</p>

<p style="text-align: right;">Page 169</p> <p>1 But I would say that, you know, NECC had a 2 division, and this rep may have been representing the 3 Ameridose side of the business, which was their 4 manufacturer. So this -- I believe these sales reps 5 may have covered both divisions.</p> <p>6 And I'm looking at this is NECC. I -- you 7 know, it's possible that -- I don't know. I mean, he 8 could have been representing Ameridose, too, which was 9 their manufacturing side.</p> <p>10 So that's a possibility. The problem is 11 that I don't know.</p> <p>12 Q. Okay. Did you have regular training 13 sessions with your employees about the guidelines and 14 ordering processes and what's forbidden and what's 15 allowed within that world for the pharmacy?</p> <p>16 A. Upon hiring somebody new, they would, of 17 course, go through orientation and training, and they 18 would have an annual performance review that would be 19 done and annual competencies that would be done. So 20 that's how we had our ongoing training and assessment 21 of people's competencies.</p> <p>22 With some of these changes, we began 23 revisiting some of our policies, and so as we made 24 changes in policies, we would also educate our staff 25 whatever the policy changes would be at our staff</p>	<p style="text-align: right;">Page 171</p> <p>1 MS. PUIG: Okay. 2 VIDEOPHOTOGRAPHER: 5:01 p.m., off the 3 record. 4 (A recess was taken.) 5 VIDEOPHOTOGRAPHER: 5:13 p.m., back on the 6 record. 7 Q. (By Mr. Stranch) We talked a little bit 8 earlier about the distinction between the for-profit 9 side and the clinics on that side that report to Mr. 10 Neu and then the hospital and the sister kind of 11 nonprofits that are directly under you as well. 12 MR. STRANCH: Wasn't that bad of a 13 question. 14 Q. (By Mr. Stranch) We talked about that 15 earlier. Do you remember us discussing that and you 16 explaining some of the distinctions to us? 17 A. Yes. I would just make one clarification, 18 if I may, to your statement. They didn't report to 19 David Neu. The clinics did not report to him. 20 Q. Okay. 21 A. They reported to Sheila on who sent that 22 e-mail. 23 Q. Okay. 24 A. We just wanted a list of the locations. 25 Q. Okay.</p>
<p style="text-align: right;">Page 170</p> <p>1 meetings. And that's how we communicated and rolled 2 out changes.</p> <p>3 Q. And how often were these staff meetings?</p> <p>4 A. We tried to meet monthly.</p> <p>5 Q. Okay.</p> <p>6 A. As much as possible.</p> <p>7 Q. And if you needed to meet more often, you 8 would schedule a special one?</p> <p>9 A. We would have a call meeting. Just right 10 in the middle of the department, yeah, have a call 11 meeting.</p> <p>12 Q. Would you agree with me that one of the 13 purposes behind USP Chapter 797 is patient safety?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And that one of the reasons why you 16 would want to do your compounding under meeting all 17 the requirements of USP Chapter 797 is patient safety?</p> <p>18 A. That's the ultimate goal is patient safety. 19 That's what we have rules and regs for is to maintain 20 a standard that will ensure patient safety best 21 outcomes.</p> <p>22 MR. STRANCH: Why don't we take 23 another short two-minute break and let us 24 see if we can consolidate some of the last 25 couple of things.</p>	<p style="text-align: right;">Page 172</p> <p>1 A. So we knew -- because these were fairly new 2 business ventures and we wanted to have contact 3 information in case anything came up.</p> <p>4 Q. Okay. And -- but my understanding of your 5 earlier testimony was that if they had questions about 6 pharmaceutical ordering or issues such as that, they 7 could deal with Mr. Neu and he could get certain 8 products for them and could help them out with that 9 process if they had questions; correct?</p> <p>10 A. If -- if something arose to that -- to that 11 end.</p> <p>12 Q. Okay. So one question I did have is if a 13 patient is going to a -- the for-profit side, one of 14 those clinics, or is coming to a clinic on the 15 nonprofit side, do they -- would they expect the same 16 level of patient safety and care?</p> <p>17 MR. TARDIO: Object to the form.</p> <p>18 THE WITNESS: That's a patient 19 perception and when you have a branded 20 product such as St. Thomas, and the 21 patient -- and this is my opinion -- the 22 patient of St. Thomas so they associate 23 because it has the St. Thomas name on it.</p> <p>24 So you, you know, it's part of the 25 same, quote/unquote, organization and</p>

<p style="text-align: right;">Page 173</p> <p>1 patient perception would -- yeah, they 2 expect that this is part of the same 3 organization.</p> <p>4 Q. (By Mr. Stranch) Okay. And they would 5 expect the same level of care at STOPNC that they 6 would receive at St. Thomas Hospital or any of the 7 other St. Thomas entities; correct?</p> <p>8 A. Based on my former comment, yes.</p> <p>9 Q. Okay. And I believe you testified 10 earlier -- and I want to get this as well -- when you 11 were -- when we discussed people that you informed 12 that you had concerns about ordering from compounding 13 pharmacies, you testified that you have no 14 recollection -- or actually, let me just ask the 15 question again differently.</p> <p>16 Did you tell anyone at STOPNC that they 17 should be leery of ordering from NECC?</p> <p>18 A. No. I had no real ongoing relationship 19 with STOPNC.</p> <p>20 Q. When you say no, are you saying you did not 21 tell anyone there or that you do not recall telling 22 anyone there?</p> <p>23 A. I do not recall telling anyone and I 24 believe -- I mean, there would be no reason for me to 25 call them. I have no recollection of ever having any</p>	<p style="text-align: right;">Page 175</p> <p>1 A. I'm trying to understand your question. 2 How is that different?</p> <p>3 Q. Let me -- let me rephrase it.</p> <p>4 A. Yeah.</p> <p>5 Q. Have you ever told anyone that you -- have 6 you ever told anyone else outside in the world that 7 you told people at STOPNC that they shouldn't order 8 from compounding pharmacies?</p> <p>9 A. No.</p> <p>10 Q. Have you ever told anyone that you told 11 employees of STOPNC that they should not order from 12 NECC?</p> <p>13 A. No.</p> <p>14 MR. STRANCH: Okay. I think that's 15 what we've got for now.</p> <p>16 MS. PUIG: Okay. I've got a couple 17 of questions. Can I go ahead of you, 18 Mr. Tardio?</p> <p>19 MR. TARDIO: Yeah. Sure. That's 20 fine.</p> <p>21 EXAMINATION</p> <p>22 BY MS. PUIG:</p> <p>23 Q. Mr. Kelvas, of course, you know me. I'm 24 Yvonne Puig, and I've got just a couple of questions. 25 Regarding David Neu, you mentioned that he</p>
<p style="text-align: right;">Page 174</p> <p>1 conversation in that regard during this time. Any 2 discussions or contact I had with them was when they 3 first opened up, and since then, there was no real 4 ongoing -- no ongoing contact or relationship with 5 them at all.</p> <p>6 Q. Okay. And I'm basically going to ask you 7 the same question, but instead of being specific to 8 NECC, do you recall having any conversations with 9 anyone at STOPNC about whether they should or should 10 not order from a compounding pharmacy?</p> <p>11 A. I have no recollection of ever having that 12 conversation with anybody from STOPNC.</p> <p>13 Q. Would you have expressed any concerns about 14 ordering from a compound pharmacy when they were 15 getting up and running?</p> <p>16 MS. PUIG: In 2000?</p> <p>17 MR. STRANCH: When he -- when he said 18 he had earlier conversations with them.</p> <p>19 THE WITNESS: That was -- back then, 20 that wasn't even an issue. It wasn't an 21 issue.</p> <p>22 Q. (By Mr. Stranch) Okay. Have you ever told 23 anyone that you warned STOPNC -- any STOPNC employee 24 or employees of STOPNC not to order compounding -- 25 from compounding pharmacies?</p>	<p style="text-align: right;">Page 176</p> <p>1 had oversight with respect to a for-profit side of the 2 house. Do you recall that testimony?</p> <p>3 A. Yes.</p> <p>4 Q. Do you know if Mr. Neu had oversight for 5 the nonprofit Dispensary of Hope?</p> <p>6 A. Yes.</p> <p>7 Q. When you describe a retail pharmacy, if 8 someone went and presented a prescription to Mr. David 9 Neu's pharmacy, would it have been filled?</p> <p>10 A. Yes.</p> <p>11 MR. STRANCH: Objection.</p> <p>12 Q. (By Ms. Puig) So a patient of St. Thomas 13 Hospital could have gone to Plaza Pharmacy to fill a 14 prescription?</p> <p>15 MR. STRANCH: Object to the form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 Q. (By Ms. Puig) Could a person who is not 18 affiliated with St. Thomas Hospital have presented a 19 prescription to Plaza Pharmacy in 2012 and had that 20 prescription filled?</p> <p>21 A. Yes.</p> <p>22 Q. A total stranger?</p> <p>23 A. Yes.</p> <p>24 Q. Yvonne Puig could have gone over there?</p> <p>25 A. Yes.</p>